

K 100947

JUN 28 2010

510(k) Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92(c).

1. Owner's Name, Address, Telephone Number, Contact Person

Name, Address, Telephone Number

Calibra Medical, Inc.
220 Saginaw Drive
Redwood City, CA 94063-4725

Contact Person

Richard J. Meader
Vice President Regulatory and Quality Affairs
Calibra Medical, Inc.
220 Saginaw Drive
Redwood City, CA 94063-4725
Direct: 1.650.298.4740
Fax: 1.650.587.8994
rmeader@calibra.com

Date Prepared

April 28, 2010

2. Trade Name

Finesse Personal Insulin Delivery Patch

3. Common Name

Disposable Insulin Infusion Pump

4. Classification Name

Pump, infusion, insulin bolus

5. Classification

Code of Federal Regulations Number	880.5725
Classification Panel	General Hospital
Product Code	OPP (primary) LZG (secondary)
Regulatory Class	Class II
Review Category	Tier 2

6. Identification of the Predicate or Legally Marketed Device

Calibra Medical, Inc. believes that the System described in this Submission is substantially equivalent to the Calibra Medical Finesse Insulin Delivery System (K093065).

7. Device Description

The Finesse Insulin Delivery System is a sterile, nonpyrogenic, single-use, external, disposable, ambulatory, insulin, bolus dosing system through which clinician-prescribed medications are delivered subcutaneously. The Finesse Insulin Delivery System is composed of a positive volume displacement drug delivery device with infusion cannula and integrated Inserter, and a drug delivery device filler. The device is adhered to the skin with a biocompatible adhesive.

The Finesse Insulin Delivery System has an integrated cannula and Inserter. The infusion cannula Inserter is used to place the cannula in the subcutaneous tissues. It contains an insertion needle located in the lumen of the infusion catheter cannula. A safety mechanism prevents premature actuation of the insertion needle mechanism to prevent injuries. Following cannula placement, the needle is retracted within the body of the Inserter to prevent sharps exposure. Once the needle is retracted, the Inserter automatically releases the Inserter from the drug delivery component.

The Finesse Insulin Delivery System materials are biocompatible plastics, elastomers, and stainless steel.

8. Intended Use

The Finesse Insulin Delivery System is indicated for the subcutaneous, bolus delivery of insulin, for the management of *diabetes mellitus* in persons requiring insulin.

9. Performance Data

Compatibility and stability studies have been completed that demonstrate the chemical, physical, microbiological stability and biocompatibility of insulin in the Finesse Insulin Delivery device for the period of time specified in the device labeling. Design verification studies have been completed that demonstrate the wear and mechanical reliability of the device for the period of time specified in the device labeling. User studies have completed that demonstrate the readability and user comprehension of the labeling.

10. Technological Comparison

The modified Finesse Insulin Delivery System is technologically identical to the predicate device. The subject device has modified labeling that allows the device to be used with insulin for up to 48 - 72 hours. Duration of usage of insulin in the device is to be consistent with labeling provided by the insulin drug manufacturer.

END OF SUMMARY



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 28 2010

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Richard J. Meader
Vice President, Regulatory and Quality Affairs
Calibra Medical, Incorporated
220 Saginaw Drive
Redwood City, California 94063

Re: K100947
Trade/Device Name: Finesse Personal Insulin Delivery Patch, Model FG 2000
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: OPP
Dated: June 16, 2010
Received: June 17, 2010

Dear Mr. Meader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

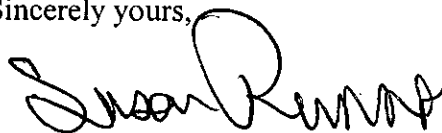
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not known.

Device Name: Finesse Personal Insulin Delivery Patch

The Finesse Insulin Delivery System is intended for the subcutaneous, bolus delivery of insulin for the management of diabetes mellitus in persons requiring insulin.

Prescription Use ✓

AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental DevicesPage 1 of 1510(k) Number: K100947